IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

POZEN INC.	§	
	§	
Plaintiff,	§	
	§	
v.	§	**CIVIL ACTION No. 6:08cv437-LED-JDL**
	§	
PAR PHARMACEUTICAL, INC.,	§	**CONSOLIDATED with**
ALPHAPHARM PTY LTD,	§	**CIVIL ACTION No. 6:09cv003 and**
TEVA PHARMACEUTICALS	§	**CIVIL ACTION No. 6:09cv182**
USA INC.,	§	
DR. REDDY'S LABORATORIES, INC.	§	
	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

This Memorandum Opinion and Order sets forth the Court's constructions for the disputed claim terms in the patents asserted by Plaintiff Pozen Inc. ("Pozen"). Pozen asserts U.S. Patent Nos. 6,060,499 ("the '499 patent"), 6,586,458 ("the '458 patent"), and 7,332,183 ("the '183 patent") and has filed an Opening Claim Construction Brief (Doc. No. 164) ("Opening"), as well as a Reply in support of Pozen's proposed constructions (Doc. No. 176) ("Reply"). Defendants Par Pharmaceutical, Inc., Alphapharm Pty Ltd., and Dr. Reddy's Laboratories, Inc. (collectively, "Defendants")[1] have filed a Responsive Claim Construction Brief (Doc. No. 170) ("Response"). A *Markman* hearing was held on February 25, 2010 (Doc. No. 184), where thirteen disputed claim terms were submitted to the Court for construction. (Doc. No. 159-2) ("Joint Claim Chart").[2] The

[1] Defendant Teva Pharmaceuticals USA, Inc. originally joined in this briefing but later entered into a stipulation with Pozen on April 14, 2010 to stay the case as to Teva based on a settlement reached by these two parties.

[2] The parties also provided the Court with a Joint Claim Construction Chart pursuant to P.R. 4-5(d).

Court entered a Provisional Claim Construction Order (Doc. No. 189) on March 26, 2010. For the reasons stated herein, the Court adopts the constructions set forth below.

BACKGROUND

This case is a patent infringement suit arising out of the Hatch-Waxman Act, 21 U.S.C. § 355. All three patents-in-suit cover a pharmaceutical formulation and corresponding methods for treating migraine headaches. The disclosed inventions relate to migraine treatment through the combination of two established drugs. The '499 and '458 patents disclose a treatment model that provides relief for migraine headaches through the simultaneous administration of two therapeutic agents in a single tablet: (1) sumatriptan[3] and (2) long-acting, non-steroidal anti-inflammatory agent ("LA-NSAID") naproxen.[4] The sumatriptan is targeted at reducing already-existing inflammation and the naproxen is targeted at reducing residual inflammation. OPENING at 4. The combination of these drugs produces "longer lasting efficacy" than the administration of either drug alone. '458 patent at 2:18–22.

This treatment model is currently sold in a single tablet as an FDA-approved pharmaceutical known as Treximet®. Defendants have each submitted an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic bioequivalent of the Pozen product. These applications challenge the patents-in-suit by asserting that they are invalid or not infringed by Defendants' proposed products. RESPONSE at 2.

[3] Sumatriptan is the preferred species in the "triptan" family of drugs, also known as 5-HT agonists, which are a subtype of cell surface receptor proteins.

[4] Naproxen, or naproxen sodium, is the preferred species of a class of non-steroidal anti-inflammatory drugs ("NSAIDs"), which binds in a highly selective way to 5-HT agonists (e.g. sumatriptan).

After Defendants filed ANDAs, Pozen filed three separate lawsuits,[5] alleging infringement of the asserted claims. Claim 1 of the '458 patent is set forth below as a representative claim, with disputed claim terms set forth in bold.

> 1. A method of treating a patient for migraine headache, comprising:
>
> a) **adminstering** a 5-HT agonist to said patient, wherein said 5-HT agonist is a triptan; and
>
> b) **administering** a **long-acting, non-steroidal, anti-inflammatory drug (LA-NSAID)** to said patient, wherein said LA-NSAID has a pharmokinetic half-life of at least 4 hours and a duration of action of at least 6 hours;
>
> wherein:
>
> i) said 5-HT agonist and said LA-NSAID are **concomitantly administered** in unit dosage form; and
>
> ii) the respective amounts of said 5-HT agonist and said LA-NSAID administered to said patient are sufficient to produce longer lasting efficacy compared to the administration of said 5-HT agonist in the absence of said LA-NSAID or the administration of said LA-NSAID in the absence of said agonist.

'458 patent at 12:6–25 (claim 1).

The '183 patent discloses a unique tablet architecture to orally administer the combination of therapeutic agents. In this delivery model, sumatriptan and naproxen are "segregated into separate layers" that dissolve in the stomach substantially independent of one another. '183 patent at 1:56–57. The specific oral dosage and the segregation of the therapeutic agents is intended to provide superior dissolution and absorption in the body. *Id*. at 1:60–62 ("The dosage forms of the invention have been found to have substantial advantages over others in terms of release properties, stability, and

[5] The separate lawsuits were consolidated into a single action in February 2009 (Doc. No. 30).

pharmacokinetic profile."). The Treximet® product contains the tablet architecture claimed by the '183 patent for the delivery of sumatriptan and naproxen. OPENING at 5. Claim 1 of the '183 patent is set forth below as a representative claim with disputed claim terms set forth in bold.

> 1. A **multilayer pharmaceutical tablet** comprising naproxen and a triptan and, wherein
>
> a) **substantially all of said triptan is in a first layer of said tablet and substantially all of said naproxen is in a second, separate layer**; and
>
> b) said first layer and said second layer are in a side by side arrangement such that the dissolution of said naproxen occurs independently of said triptan.

'183 patent at 18:30–37 (claim 1).

The parties present thirteen disputed claim terms for construction. The following terms are presented from the '499 patent: 1) "by administering," "administering," and "administered"; 2) "concomitantly administering," "concomitantly administered," and "concomitant administration"; 3) "long-acting, nonsteroidal, anti-inflammatory drug (LA-NSAID);" 4) "said LA-NSAID is naproxen." The following terms are presented from the '458 patent: 5) "a long-acting, nonsteroidal, anti-inflammatory drug (LA-NSAID)"; 6) "concomitantly administered"; 7) "adminstering," and "administered"; 8) "wherein said LA-NSAID is naproxen or a pharmaceutically acceptable salt thereof"; 9) "said LA-NSAID is naproxen"; 10) "wherein said naproxen is in the form of a sodium salt." The following terms are presented from the '183 patent: 11) "A multilayer pharmaceutical tablet"; 12) "substantially all of said triptan is in a first layer of said tablet and substantially all of said naproxen is in a second, separate layer"; and 13) "administering to said patient."[6]

[6] The parties have also agreed to a number of constructions. *See* JOINT CHART (Doc. No. 159-1).

Due to the significant overlap of the terms as they are presented among the three patents, the Court will issue constructions for the following "groups" of terms:[7] 1) "administering" and its permutations; 2) "concomitant administration" and its permutations; 3) "long-acting, non-steroidal, anti-inflammatory drug," or "LA-NSAID"; 4) "said LA-NSAID is naproxen"; 5) "a multilayer pharmaceutical tablet"; 6) "substantially all of said triptan is in a first layer of said tablet and substantially all of said naproxen is in a second, separate layer."

LEGAL STANDARD

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (hereinafter "Phillips") (quoting *Innova/Pure Water Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Under *Markman v. Westview Instruments, Inc.*, the court construes the scope and meaning of disputed patent claims as a matter of law. 517 U.S. 370, 373 (1996). In claim construction, courts examine the patent's intrinsic evidence to define the patented invention's scope. *See id.*; *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 861 (Fed. Cir. 2004); *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). This intrinsic evidence includes the claims themselves, the specification, and the prosecution history. *See Phillips*, 415 F.3d at 1314; *C.R. Bard, Inc.*, 388 F.3d at 861. Courts give claim terms their ordinary and accustomed meaning as understood by one of ordinary skill in the art at the time of the invention in the context of the entire patent. *Phillips*, 415 F.3d at 1312–13; *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1368 (Fed. Cir. 2003).

The claims themselves provide substantial guidance in determining the meaning of particular

[7] Such groupings promote efficiency and track the manner in which they were argued at the claim construction hearing.

claim terms. *Phillips*, 415 F.3d at 1314. First, a term's context in the asserted claim can be very instructive. *Id*. Other asserted or unasserted claims can also aid in determining the claim's meaning because claim terms are typically used consistently throughout the patent. *Id*. Differences among the claim terms can also assist in understanding a term's meaning. *Id*. For example, when a dependent claim adds a limitation to an independent claim, it is presumed that the independent claim does not include the limitation. *Id*. at 1314–15.

"[C]laims 'must be read in view of the specification, of which they are a part.'" *Id*. (quoting *Markman v. Westview Instruments, Inc*., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc)). "[T]he specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Id*. (quoting *Vitronics Corp. v. Conceptronic, Inc*., 90 F.3d 1576, 1582 (Fed. Cir. 1996)); *Teleflex, Inc. v. Ficosa N. Am. Corp*., 299 F.3d 1313, 1325 (Fed. Cir. 2002). This is true because a patentee may define his own terms, give a claim term a different meaning than the term would otherwise possess, or disclaim or disavow the claim scope. *Phillips*, 415 F.3d at 1316. In these situations, the inventor's lexicography governs. *Id*. Also, the specification may resolve ambiguous claim terms "where the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone." *Teleflex*, 299 F.3d at 1325. Nonetheless, "'[a]lthough the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims.'" *Comark Commc'ns, Inc. v. Harris Corp*., 156 F.3d 1182, 1187 (Fed. Cir. 1998) (quoting *Constant v. Advanced Micro-Devices, Inc*., 848 F.2d 1560, 1571 (Fed. Cir. 1988)); *see also Phillips*, 415 F.3d at 1323. The prosecution history is another tool to supply the proper context for claim

construction because a patent applicant may also define a term in prosecuting the patent. *Home Diagnostics, Inc. v. Lifescan, Inc*., 381 F.3d 1352, 1356 (Fed. Cir. 2004) ("As in the case of the specification, a patent applicant may define a term in prosecuting a patent.").

Although extrinsic evidence can be useful, it is "'less significant than the intrinsic record in determining the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc*., 388 F.3d at 862). Technical dictionaries and treatises may help a court understand the underlying technology and the manner in which one skilled in the art might use claim terms, but technical dictionaries and treatises may provide definitions that are too broad or may not be indicative of how the term is used in the patent. *Id*. at 1318. Similarly, expert testimony may aid a court in understanding the underlying technology and determining the particular meaning of a term in the pertinent field, but an expert's conclusory, unsupported assertions as to a term's definition is entirely unhelpful to a court. *Id*. Generally, extrinsic evidence is "less reliable than the patent and its prosecution history in determining how to read claim terms." *Id*.

DISCUSSION

I. "administering" and its permutations[8]

Plaintiff's Proposed Construction	Defendants' Proposed Construction
Ordinary and customary meaning. Alternatively, "to mete out."	Putting into a patient

The patents-in-suit contain the terms "by administering," "administering," "administered," and "administering to said patient." For ease of discussion, the Court will collectively discuss the

[8] The term "administering" and its permutations is contained in claims 1, 2, 3, 6, 7 and 9–27 of the '499 patent; claims 1, 2, 5, and 6–24 of the '458 patent; and claims 13–18 and 20 of the '183 patent.

representative term "administering" and permutations of this term should be given the same construction in each patent. *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003) ("we presume, unless otherwise compelled, that the same claim term in . . . related patents carries the same construed meaning").

Pozen contends that the claim term should be given its ordinary and customary meaning and no further construction is necessary because a person of ordinary skill in the art would readily understand the meaning of "administering" and its permutations. OPENING at 9–10. Pozen argues that if the Court is inclined to provide a construction, "administering" should mean "to mete out," as it is set forth in Webster's general purpose dictionary. *Id.* at 10.

Defendants respond that the goal of the '499 and '458 patents is to treat migraines in patients, and this can only be accomplished when the drug is "put into a patient." RESPONSE at 6. Therefore, Defendants argue that the term must be construed more narrowly than its ordinary meaning to comport with the patent's description of the invention. Defendants cite to passages from the claim language and relevant specifications to argue that when the claims are read in the context of offering clinical treatment, "administering" should mean putting the drug into a migraine patient. *Id.* at 6.

As discussed at the hearing, it appears that Defendants are asking the Court to construe "administering" as it appears in non-asserted method claims only. This approach is unavailing at the current juncture because Pozen is not alleging infringement of the method claims underlying Defendants' argument. For example, Defendants contend that claim 3 of the '499 patent and claim 5 of the '458 patent teach that "administering" means "putting the drug in a migraine patient." Defendants maintain that for these claims, this is the only definition that allows for the patents' claimed therapeutic effect. Evaluating the patents as a whole, however, this context is not

determinative where Pozen is not asserting these particular claims and the claim term can be understood without including Defendants' proposed step that must occur "in a method for treating a migraine patient." *See, e.g.*, '499 patent at 13:39. The manner in which Defendants present the dispute frames a question as to when or how unasserted claims require a step— putting the drug into the patient— to perform the medical method.

The Court declines to narrow the meaning of the claim term. Instead, the Court considers the intrinsic record for both the method and composition claims. Pozen has only asserted composition and therapeutic package claims against Defendants, and the Court finds that "administering" and all of its permutations (including those in unasserted method claims) have an ordinary and customary meaning. Abiding by the "heavy presumption" that a claim term carries its ordinary and customary meaning, *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002), one of ordinary skill in the art would understand "administering" and its permutations as conveying its ordinary meaning in the context of the claim language. *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 (Fed. Cir. 2003). Defendants' proposed construction, "putting into," does not appear in the '499 patent and the Federal Circuit makes clear that additional limitations should not be read into the claim. *Innova/Pure Water*, 381 F.3d at 1117–18. The claim terms are the primary source for the meaning of the claim, and "[a]bsent a clear disavowal or contrary definition in the specification or prosecution history, the patentee is entitled to the full scope of its claim language. *Home Diagnostics*, 381 F.3d at 1358; *Enercon GmbH v. Int'l Trade Comm'n*, 151 F.3d 1376, 1384 (Fed. Cir. 1998) (requiring that absent some special definition, claim terms are to be given their ordinary meaning). No such special definition or disavowal is found here.

As discussed at the hearing, this readily-understandable term would include giving a patient a drug in any normal manner (i.e., providing a tablet to a patient under circumstances where it is reasonable to believe that a patient is going to take the tablet). Accordingly, the Court finds that the proper and most internally-consistent construction of the term "administering," and its relevant permutations, is its ordinary and customary meaning. For the sake of further clarity, the Court also determines that the ordinary and customary meaning of "administering" is equivalent to the general purpose dictionary definition of "administer." Should the meaning of "administering" be called into question at trial, "to mete out" is an alternative reflection of the claim language.

II. "concomitant administration" and its permutations[9]

The '499 and '458 patents both contain the claim terms "concomitantly administering," "concomitantly administered," and "concomitant administration." In order to fully assess the context in which "concomitant administration" and its permutations is presented, the Court assesses the term separately as it is used in each patent.

[9] The term "concomitant administration" and its permutations are contained in claims 1, 2, 3, 5–8, and 9–27 of the '499 patent and claims 1, 2, 5, and 6–24 of the '458 patent.

A. The ‘499 Patent

Plaintiff’s Proposed Construction	Defendants’ Proposed Construction
Simultaneous administration; or administration of a second drug for migraine relief while a first drug for migraine relief is present in a therapeutically effective amount; or administration of a 5-HT agonist and NSAID such that the effective plasma levels of the NSAID will be present in a subject from about one hour to about 12–24 hours after the onset of migraine or onset of precursor symptoms of a migraine.	Putting into a patient two (or more) compositions (i.e., drugs) such that: a) the drugs are put into a patient at the same time; or b) the second drug is put into a patient while the first drug is present in the patient in a therapeutically effective amount, or c) putting into a patient a 5-HT agonist and NSAID such that effective plasma levels of the NSAID will be present in a subject from about one hour to about 24 hours after the onset migraine or onset of precursor symptoms of a migraine.

Pozen and Defendants present the same arguments discussed in the previous section as to disputed claim term “administering” and its permutations. Having already provided a construction for this term in section I, *supra*, the Court incorporates the foregoing discussion and now turns to the meaning of “concomitantly.”

Pozen contends that the inventor acted as his own lexicographer in the ‘499 patent specification and defined “concomitant administration” as “simultaneous administration,” “co-timely administration,” or “coordinated administration.” OPENING at 12 (citing ‘499 patent at 7:37–8:5). Pozen also suggests that the language in the specification aligns with the ordinary and customary meaning of the term, namely “simultanelous administration.”

Defendants generally “agree with Pozen that the proposed construction for this term should be nothing more than the express definition of ‘concomitant administration’ from the ‘499 patent specification,” but Defendants dispute whether Plaintiff accurately characterizes the specification.

RESPONSE at 11–12. Defendants maintain that to have a concomitant administration, there must be at least two drugs administered. After the Provisional Claim Construction Order was issued, Defendants moved the Court to clarify that "simultaneous administration" should alternatively mean "administration of a second drug for migraine relief," with the requested construction designating the combination of therapeutic agents and the time required to alleviate symptoms. (Doc. No. 204).

As suggested by both parties, the '499 patent specification recites an express definition that describes the drug administration: "For convenience, the term 'concomitant administration' shall refer to 'simultaneous administration,' 'co-timely administration, or 'coordinated administration.'" *See* '499 patent at 8:1–5. Since this is an instance where the inventor has clearly defined his own terms, the inventor's lexicography will govern the construction provided for "concomitant administration." *Phillips*, 415 F.3d at 1316. The '499 patent prosecution history is also consistent as to the explicit definition. Accordingly, the Court finds that "concomitant administration" means "simultaneous administration," and further extrapolating "concomitantly" in the context of the '499 specification, the Court finds "concomitantly" to mean "simultaneously."

Alternatively, the Court adopts additional language[10] proposed first by Pozen at the *Markman* hearing, and then by Defendants in the Motion to Clarify the Provisional Claim Construction Order (Doc. No. 204). The '499 patent specifications supports a broad understanding of "simultaneously" that includes a "co-timely" or "coordinated" administration. *See* '499 patent at 7:37–40, 46–51. It necessarily follows that a "simultaneous administration" would include the limitations provided for

[10] This additional language reads: "or administration of a second drug for migraine relief while a first drug for migraine relief is present in a therapeutically effective amount or administration of a 5-HT agonist and NSAID such that the effective plasma levels of the NSAID will be present in a subject from about one hour to about 12–24 hours after the onset of migraine or onset of precursor symptoms of a migraine." (Doc. No. 225 at 2, n.1).

in "co-timely"[11] and "coordinated"[12] administrations, such as the administration of a second drug. Therefore, the administration details disclosed in the '499 patent specification are incorporated as an alternative construction for "simultaneous." The proper construction of the term "concomitant administration" and its permutations in the '499 patent is "simultaneous administration," or "administration of a second drug for migraine relief while a first drug for migraine relief is present in a therapeutically effective amount," or "administration of a 5-HT agonist and NSAID such that the effective plasma levels of the NSAID will be present in a subject from about one hour to about 12–24 hours after the onset of migraine or onset of precursor symptoms of a migraine."

B. The '458 Patent

Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
Given in close enough temporal proximity to allow their individual therapeutic effects to overlap.	Putting into a patient two (or more) compositions (i.e., drugs) such that they are "given in close enough temporal proximity to allow their individual therapeutic effects to overlap."

The parties agree that claims using "concomitantly" and its permutations in the '458 patent are expressly defined, and they only dispute the meaning of "administration." Incorporating the discussion of "administering" as provided in section I, *supra*, there is no outstanding dispute for this claim term. Therefore, the Court adopts the definition provided by the inventor in the '458 patent at column 2, lines 24–30 and finds that the proper construction of the term "concomitant

[11] "Co-timely" is described in the'499 patent specification as: "administration of a second drug for migraine relief while a first drug for migraine relief is present in a therapeutically effective amount." '499 patent at 7:37–40 .

[12] "Coordinated" is described in the '499 patent specification as: "administration of an NSAID such that effective plasma levels of the NSAID will be present in a subject from about one hour to about 12–24 hours after the onset of migraine or onset of precursor symptoms of a migraine." '499 patent at 7:46–51.

administration" in the '458 patent is "given in close enough temporal proximity to allow their individual therapeutic effects to overlap."

III. "long-acting, nonsteroidal, anti-inflammatory drug (LA-NSAID)"[13]

Plaintiff's Proposed Construction	Defendants' Proposed Construction
An NSAID with a pharmacokinetic half-life of at least about 4–6 hours and preferably about 8–14 hours and a duration of action equal to or exceeding about 6–8 hours.	A non-steroidal anti-inflammatory drug with a pharmacokinetic half-life of at least about 4–6 hours and a duration of action equal to or exceeding about 6–8 hours.

The '499 and '458 patents contain the term "long-acting, non-steroidal, anti-inflammatory drug (LA-NSAID)." Pozen contends that the '499 and '458 patent specifications provide an express definition for the claim term and the claims and files histories do not contradict this definition. OPENING at 19. Defendants argue that Pozen is impermissibly reading a limitation from the specification into the claim terms. RESPONSE at 13–14 (citing relevant case law). Defendants particularly object to specification language in Pozen's proposed construction that reads "preferably about 8–14 hours" because the inclusion of the "preferably" limitation is "superfluous" and "creates confusion where none exists." RESPONSE at 13.

The Court does not read the additional language—"preferably about 8–14 hours"—to render the claim scope uncertain. Instead, the inventor's specific definition, should be honored in the meaning of the claim term. Defendants argue that this language constitutes a preferred embodiment that cannot be imported to alter the scope of the patentee's claims, but an examination of the '458 specification reveals a special definition, not a preferred embodiment. The Federal Circuit has extensively discussed the fine distinction between the "twin axioms" regarding the role of the

[13] As defined herein, the term "long-acting, nonsteroidal, anti-inflammatory drug (LA-NSAID)" is contained in claims 1–8 of the '499 patent and claims 1, 3, 4, 5, 25 and 28 of the '458 patent.

specification in claim construction: "On one hand, claims 'must be read in view of the specification, of which they are a part. On the other hand, it is improper to read a limitation from the specification into the claims." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 904 (Fed. Cir. 2004); *Comark Commc'ns*, 156 F.3d at 1187 ("[T]here is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification.").

At the outset, the "preferably" clause in Pozen's proposed construction does not appear to narrow what is present in the claim terms. While this additional language does introduce the patentee's preferred time span for the drug's optimal effect, it is clear from the wording that the "at least about 4–6 hours" is the time span that is ultimately controlling. With the minimum of "at least about 4–6 hours"defining the metes and bounds of what is claimed, the patentee's "preference" does not introduce uncertainty because the scope of the claim is already defined. Put another way, the "at least" half-life language encompasses the later half life language ("preferably about 8–14 hours ") to make the minimum half-life apparent to one of skill in the art. One of skill in the art would understand that the definition has a minimum, as well as a preferred range of action, for NSAIDs.

Therefore, the Court finds that the proper construction of the term "long-acting, nonsteroidal, anti-inflammatory drug (LA-NSAID)" is "an NSAID with a pharmacokinetic half-life of at least about 4–6 hours and preferably about 8–14 hours and a duration of action equal to or exceeding about 6–8 hours."

IV. "said LA-NSAID is naproxen"[14]

Plaintiff's Proposed Construction	Defendants' Proposed Construction
(S)-6-methoxy-α-methyl-2-naphthaleneacetic acid in any pharmaceutically acceptable form.[15]	(S)-6-methoxy-α-methyl-2-naphthaleneacetic acid; does not mean (S)-6-methoxy-α-methyl-2-naphthaleneacetic acid, sodium salt.
(S)-6-methoxy-α-methyl-2-naphthaleneacetic acid in any pharmaceutically acceptable form or specifically in the form of a pharmaceutically acceptable salt.[16]	(S)-6-methoxy-α-methyl-2-naphthaleneacetic acid or a pharmaceutically acceptable salt thereof.
(S)-6-methoxy-α-methyl-2-naphthaleneacetic acid in any pharmaceutically acceptable form is specifically in the form of a sodium salt.[17]	The chemical name for naproxen is (S)-6-methoxy-α-methyl-2-naphthaleneacetic acid sodium salt; does not mean (S)-6-methoxy-α-methyl-2-naphthaleneacetic acid.

The '499 and '458 patents contain the term "said LA-NSAID is naproxen." The parties' primary dispute as to this term is whether the term "naproxen" should be construed to include all pharmaceutically acceptable forms of the active agent, including its free acid forms, isoforms, and salt forms. As noted in the above chart, Pozen proposes alternate constructions for "naproxen"

[14] The term "said LA-NSAID is naproxen" is contained in claims 13, 14, 15, and 26 of the '499 patent and claims 10, 11, 12, 23, 26 and 29 of the '458 patent.

[15] The parties propose a construction for the claim term based on the context in which it is presented in claims 15 and 26 of the '499 patent and claims 12, 23, 26, and 29 in the '458 patent. Pozen refers to this context as "Term Number 81."

[16] The parties propose an alternate construction for the claim term based on the context in which it is presented in claim 11 of the '458 patent: "said LA-NSAID is naproxen or a pharmaceutically acceptable salt thereof." Pozen refers to this context as "Term Number 77."

[17] The parties propose an alternate construction for the claim term based on the context in which it is presented in claim 24 of the '458 patent: "said LA-NSAID is naproxen in the form of a sodium salt." Pozen refers to this context as "Term Number 82."

based on where the claim term appears. The discussion herein will focus on contexts where Pozen argues for the broadest possible construction.[18] *See* OPENING at 20–22.

Pozen contends that "naproxen" would be understood to be a generic designation for (S)-6-methoxy-α-methyl-2-naphthaleneacetic acid and its pharmaceutically acceptable forms because it was known at the time of the invention that naproxen and naproxen sodium contain the same active moiety. *Id*. at 20–22 (citing '458 patent at 8:62–66).

Defendants contend that the plain language of the claims supports a construction of "naproxen" that interprets naproxen and its salts to be distinct chemical entities with different properties. Defendants point out that the specification and claim language successfully distinguishes between naproxen and its sodium salt, thus inferring that the general use of "naproxen" excludes its salt forms. RESPONSE at 17–18. For example, Defendants identify distinguishing specification language discussing different "cautionary guideline[s]" concerning different maximum dosages of naproxen and naproxen sodium. *Id*. at 18 (citing '499 patent at 9:30–41 and '458 patent at 9:24–26). Similarly, under a theory of claim differentiation, Defendants point out that in claim 13 of the '499 patent, Pozen specifically claimed "naproxen sodium" (i.e. the pharmaceutically acceptable salt form) as a separate alternative to the acid form disclosed in claims 15 of the '499 patent and claims 12, 26, and 29 of the '458 patent. RESPONSE at 16.

A review of the claims, especially in light of the specification, suggests that there is ambiguity as to whether "naproxen" was intended to encompass other forms of the active moiety. The structure of some of the claims seems to support the premise that naproxen was used in a

[18] For Term Number 81, Pozen proposes "(S)-6-methoxy-α-methyl-2- naphthaleneacetic acid *in any pharmaceutically acceptable form*," but its briefing as to this term focuses on a proposed construction that includes "any pharmaceutically acceptable *salt form* of the active moiety naproxen, including the *free acid form* of naproxen and naproxen sodium." OPENING at 20 (emphasis added).

generic sense to include any pharmaceutically acceptable form, but other claims and language in the specifications can be read to identify distinct forms of naproxen acid and naproxen salt. Defendants' claim differentiation arguments are not determinative because despite the apparent inconsistency in the claims, Pozen offers an alternative understanding of the claims that supports its position. Pozen explains the inconsistent use of "naproxen" by arguing that the scope of the claim term is premised on whether it is an independent or dependent claim. As illustrated in the briefing, independent claim 23 of the '458 patent recites: "[t]he method or composition of claim 22, wherein *said LA-NSAID is naproxen*." '458 patent at 14:4–5 (emphasis added). As stated, claim 23 presumably refers to "naproxen" in a generic sense, but claim 24— which is dependent on claim 23— specifically refers to "said naproxen" in a salt form. Applying principles requiring that a dependent claim incorporate by reference all the limitations of the claim to which it refers, Pozen counters that claim 24 should be given the broader scope present in claim 23. OPENING at 20–21 (citing 35 U.S.C. § 112 ¶ 4 (2008) ("A Claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.")). Therefore, weighing the claim interpretation principles presented by both parties, the Court finds that the claims fail to convey a clear meaning of the term.

Turning next to the specification, the controlling inquiry is what one skilled in the art of these patents would understand the chemical composition of "naproxen" to be in light of the claims and specification around the time of the invention. *Phillips*, 415 F.3d at 1313 (citing *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)). A review of the specification again makes clear that "naproxen" is used both in a generic sense and as a distinct salt form depending on which claim is being described and whether the specification is describing the

preferred embodiment.[19] The patentee's failure to choose a consistent meaning dictates that "naproxen" should be accorded the ordinary meaning ascertainable to one of ordinary skill in the art. *See Johnson Worldwide Assoc., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed. Cir. 1990). At the hearing, both parties acknowledged that such a generally accepted meaning for "naproxen" is (S)-6-methoxy-α-methyl-2- naphthaleneacetic acid, as it is identified in the 1989 edition of the *Merck Index*.[20] Where, as here, there is some ambiguity that could result from intrinsic review, technical dictionary definitions can be useful guideposts and indicative as to how one skilled in the art would understand a technical term. *Phillips*, 415 F.3d at 1322–24; *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("Extrinsic evidence may also be considered, if needed, to assist in determining the meaning or scope of technical terms in the claims.").

Importantly, the *Merck Index* has a definition for "naproxen" that lists the chemistry of the acid, but is also lists two salts (including the sodium salt) under the same entry. This extrinsic evidence, which would be available to one of ordinary skill at the time of the invention, supports Pozen's position that the term "naproxen" should be understood to include pharmaceutically acceptable salt forms. A fair reading of the *Merck Index*, however, does not include "all pharmaceutically acceptable forms of the active moiety naproxen." Therefore, this extrinsic definition, coupled with the lack of a broadened definition in the specification, supports that the acid and its salts are both correctly referred to as "naproxen," but the present record does not support

[19] For example, all of the '499 and '458 patent examples are directed to a composition comprising sumatriptan succinate and naproxen sodium– the salt form of naproxen. *E.g.*, '458 patent at 10:3–15.

[20] The Merck Index is a reference for chemists that is akin to a dictionary encyclopedia of chemical compounds. This technical dictionary contains a list of almost all known chemicals and their physical properties. *See The Merck Index*, 11th ed. at 1014 (1989).

extending the meaning of the claim term to include every possible derivative of the acid. Accordingly, the Court finds that the proper construction of the term "said LA-NSAID is naproxen," is "said LA-NSAID is (S)-6-methoxy-α-methyl-2- naphthaleneacetic acid or a pharmaceutically acceptable salt thereof."

V. "a multilayer pharmaceutical tablet"[21]

Plaintiff's Proposed Construction	Defendants' Proposed Construction
A pharmaceutical tablet with multiple distinct areas.	A pharmaceutical tablet with at least two separate, distinct layers; it does not include: tablets that are admixtures; any dosage forms other than tablets; tablets in which one drug is in a core and surrounded by a layer or coating containing the second drug; and tablets containing multiple drug release pellets or microparticles.

The '183 patent contains the term "a multilayer pharmaceutical tablet." The parties primarily dispute the meaning of the term "layer," and therefore the Court will focus its discussion on this claim term. Pozen acknowledges that the relevant claims are necessarily limited to a very specific tablet architecture. OPENING at 25. As recognized by both parties, the patentee disclaimed "admixtures; any dosage forms other than tablets; tablets in which one drug is in a core and surrounded by a layer or coating containing the second drug; and tablets containing multiple drug release pellets or microparticles." OPENING, EXH. 10 at 6, EXAMINER AMENDMENT AND RESPONSE (April 5, 2007)). Despite this disclaimer, Pozen contends that a tablet "with multiple distinct areas" was not disclaimed and is supported by the specification. OPENING at 26. This proposed construction includes multiple layers and does not limit "a multilayer pharmaceutical tablet" to just two layers.

[21] The term "a multilayer pharmaceutical tablet" is contained in claims 1–20 of the '183 patent.

Pozen points to the prosecution history where the examiner used the term "areas" when allowing the claim and argues that the examiner's usage supports a construction where "layer" need not have any specific geometric shape and can be described as an "area." REPLY at 9; OPENING, EXH, 12 at 4, NOTICE OF ALLOWABILITY (Nov. 20, 2007).

Defendants argue that the plain language of the '183 patent clearly requires a tablet with two distinct layers of triptan and NSAID. Defendants point to language in the claims, the '183 patent specification, and the prosecution history to contend that the disclosed tablet architecture is geometrically limited. *See* RESPONSE at 23–25.

Given that Pozen does not appear to dispute the disclaimed tablet architectures identified in the second part of Defendants' proposed construction, the Court adopts these limitations but declines to include this language in its construction for the claim term. Thus, in light of the Patent Office's 35 U.S.C. § 103 rejection, the claimed tablet architecture does not encompass the following dosage forms: "admixtures; any dosage forms other than tablets; tablets in which one drug is in a core and surrounded by a layer or coating containing the second drug; and tablets containing multiple drug release pellets or microparticles." Pozen will be held to the patent applicants' description of the claimed invention as detailed in the specification language and prosecution history. *See Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003) ("[T]he notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent.").

The relevant claim language makes clear that triptan is located in a "first layer" of the tablet and naproxen is located in a "second, separate layer." *See* '183 patent at 18:30–38 (claim 1). Importantly, there is no mention of "areas." The claims themselves repeatedly discuss "layers" and

they appear to use the term in a manner that is consistent with the understanding that it refers to a physical structure rather than to an amount of a particular material.[22] A plain meaning interpretation is further supported by the '183 patent specification. For example, the '183 patent specification recites, "[t]he main characteristics of the dosage forms are that they are in the form of tablets in which the triptan and NSAID are maintained in separate distinct layers. . ." '183 patent at 3:47–49. Figure 1 in the specification further depicts the claimed invention as having a geometric layers without any depiction of "areas." *Id*. at 3:32–40, Fig. 1.

Based on these intrinsic representations, the Court interprets "layer" to imply a variable geometric structure corresponding to one of the tablet's two therapeutic agents. Pozen's proposal appears to broaden the term in a manner that would not require any geometric boundaries. Having reviewed the patentee's exchange with the Examiner in response to the § 103 rejection, the Court concludes that the claims were eventually allowed after Pozen limited its tablet structure to at least two layers. To give effect to Pozen's proposed construction (i.e. "distinct areas") risks impermissible ambiguity, especially if Pozen accuses a tablet with a coating of one drug and a core of another. Even with Pozen's suggestion that the claims require a "side-by side-arrangement," there is uncertainty as to whether the coated tablet type arrangement could be considered "distinct areas."[23] Therefore, in order to provide a construction that is most clearly supported by the intrinsic

[22] The '183 patent claims consistently relate to the geometric relationship of additional structures termed "layers." For example, claim 6 defines a particular symmetrical juxtaposition of the two layers. '183 patent at 18:48–53 (claim 6). Claim 7 refers to a planar surface contact between the two layers. *Id.* at 54–56 (claim 7). Claim 8 refers to at least one additional layer separating a first and second. *Id*. at 61–63 (claim 10).

[23] Pozen's definition of "layer" potentially encompasses Panel B of Figure 1 of the '183 patent, a coated tablet type arrangement, which was explicitly disclaimed during prosecution. In the disavowed tablet structure, Pozen made clear that the '183 patent does not encompass a tablet in which one drug is in a core and surrounded by a layer or coating containing the second drug. *See Scimed Life Sys., Inc. v. Advanced Cardiovascular Sys. Inc.*, 242 F.3d 1337, 1340–42 (Fed. Cir. 2001).

evidence, the Court finds that the proper construction of the term "a multilayer pharmaceutical tablet" is "a pharmaceutical tablet with at least two separate, distinct layers."

VI. "substantially all of said triptan is in a first layer of said tablet and substantially all of said naproxen is in a second, separate layer"[24]

Plaintiff's Proposed Construction	Defendants' Proposed Construction
At least 90%, and preferably greater than 95%, of the total therapeutic agent present in the tablet is included within one distinct layer. "a first layer" means one or more distinct areas of triptan. "a second, separate layer" means one or more distinct areas of naproxen. The rest of the phrase is ordinary and customary meaning in light of the agreed construction for naproxen.	At least 90% of the total amount of triptan in the tablet is in a first distinct layer of the tablet and at least 90% of the total amount naproxen in the tablet is in a second distinct layer of the tablet.

The '183 patent contains the term "substantially all of said triptan is in a first layer of said tablet and substantially all of said naproxen is in a second, separate layer." The parties agree that the patentee chose to be its own lexicographer by providing a specific definition for "substantially all."[25] *See* OPENING at 27; RESPONSE at 27. The parties dispute, however, whether to include the "preferably greater than 95%" language. The Court concludes that by specially defining "substantially all" and using it in the claim, the patentee instructed those skilled in the art as to how the claim should be read. *See* '183 patent at 2:43–46.

[24] The term "substantially all of said triptan is in a first layer of said tablet and substantially all of said naproxen is in a second, separate layer" is contained in claim 1 of the '183 patent.

[25] As acknowledged by both parties, the '183 patent specification, provides: "The term 'substantially all' indicates that at least 90% and preferably greater than 95% of the total therapeutic agent present in the tablet is included within one distinct layer." '183 patent at 2:43–46.

The remaining claim construction dispute concerns the meaning of the phrases "a first layer" and "a second, separate layer."[26] The parties' dispute revolves around whether the terms "first" and "second" refer to (A) triptan and naproxen as first and second agents that must be kept separate but could be present in multiple "first" and "second" layers of each agent, or (B) two physical but separate layers.

Pozen contends that "first" and "second" refer to the drugs— naproxen and triptan— and not to the number of layers. OPENING at 27–28. Pozen particularly argues that different words or phrases used to describe the tablet in separate claims is presumed to indicate that dependent claim 9 is differentiated from claims 1–8. Pozen points out that the dependent claim is drawn to a "bilayer dosage" for the preferred embodiment and contends that the use of "bilayer" is distinguishable from "multilayer." Specifically, Pozen infers that one of skill in the art would understand that the broader claims contain more than two layer of drugs, and therefore, Defendants' bilayer dosage construction should be rejected. OPENING at 28 (citing *Karlin Tech, Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971–72 (Fed. Cir. 1999)).

Defendants contend that the language of the claim, the specification and the prosecution history all support the conclusion that all of the naproxen is found in one single layer and all the triptan is found in a single second separate layer. RESPONSE at 26–28 (citing '183 patent at 2:4–6 and 3:34–35). Under Defendants' proposed construction for claim 1, the terms "first" and "second" are understood to refer to layers, not agents.

[26] The parties continue to dispute whether "layer" should be defined as "distinct areas" or by a particular geometry associated with planar "layers." Having already discussed these proposals in section V, *supra*, the Court will not again address these arguments in this section. Instead, the previous discussion is incorporated into the Court's construction for this claim term.

The Court finds that the terms "first" and "second," as used in claim 1 of the'183 patent, refer to first and second physical layers. First, by specially defining "substantially all" in the specification, the patentee instructed those skilled in the art that the agents would be present in "one distinct layer." *See Cook Biotech Inc. v. Acell, Inc.*, 460 F.3d 1365, 1372 (Fed. Cir. 2006) (recognizing that the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification).Where, as here, the inventor provided a definition for "substantially all," that special definition will govern. *Phillips*, 415 F.3d at 1313. While there is no explicit disclaimer of multiple layers of each agent in the intrinsic evidence, neither is there any specific teaching or reference to such a structure. If the patentee intended to describe and claim a tablet architecture where all the triptan and naproxen were present in multiple separate areas, the patentee could have more acutely defined such geometry in the specification. Instead, the specification states that "[s]ubstantially all of the triptan is found in one layer of the tablet and substantially all of the naproxen is found in a second, separate layer." '183 patent at 2:4–6. The disclosed examples further illustrate this architecture because the superior performance of the tablet is linked to circumstances where there are first and second physical layers of the drug when it was made and tested. *See, e.g.*, '183 patent at 2:4–11 (discussing the superior properties of the tablet arrangement and describing "two layers" that allow for optimal dissolution); *see also* '183 patent at 18:41–49 and 18:54–63 (disclosing the arrangement of layers in the preferred embodiment).

Second, the Court also rejects Pozen's "multilayer" versus "bilayer" distinction in claims 1 and 9 because the different descriptions are reconcilible with the teachings of the '183 patent specification. The specification points out that the tablets can include layers of materials other than

triptan or naproxen. *See, e.g.*, '183 patent at 2:65–3:4 (describing "a barrier layer or coating which prevents the therapeutic agents from interacting with one another"). Thus, "multilayer" can refer to a tablet that has (1) a single layer of triptan, (2) a single layer of naproxen, and (3) additional layers of inert material that separates the naproxen and triptan. Claim 1, which uses the term "comprising" would read on a tablet that had one layer each of triptan and naproxen and a third layer of another therapeutic agent since it is limited to multilayer forms. Claim 9, however, is of different scope since it would exclude the third agent because it is limited to bilayer. In either case, however, the naproxen and the triptan could be present in "one distinct layer." Thus, claim 9 and claim 1 can be understood to be of different scope even if both would require that all the naproxen be in one single layer and all the triptan be one second single layer.

Lastly, it is axiomatic that each word in a claim is presumed to have some meaning. Pozen contends that the terms "first" and "second" refer to the triptan and the naproxen and do not further define or restrict the number of layers. Thus, in Pozen's view, the multilayer tablet can have many layers of triptan and many separate layers of naproxen. If that were so, claim 1 could have simply read "substantially all said triptan is in a layer of said tablet and substantially all of said naproxen is in a separate layer." Such language would have expressed exactly what Pozen now contends is the case—a structure with any number of layers— so long as the two compounds were found in different layers. Nonetheless, that is not how the claim was drafted. Instead the patentee chose to insert "first" and "second" into claim 1 before "layer" and "separate layer." To give "first" and "second" any meaning at all, they must refer to a first layer and a second layer and not to the two different compounds.

Accordingly, the Court finds that the definition for this term should be "at least 90%, and preferably greater than 95%, of the total triptan present in the tablet is included within one distinct layer and at least 90%, and preferably greater than 95%, of the naproxen present in the tablet is included within a second distinct layer."

CONCLUSION

For all the foregoing reasons, the Court construes the disputed claim language in this case in the manner set forth above. For the ease of reference, the Court's claim interpretations are set forth in a table attached to this Memorandum Opinion and Order as an Appendix.

The construction set forth for the disputed term "concomitant administration" and its relevant permutations was clarified in Section II. Finding that the additional language was supported by the intrinsic record, Defendants' Motion to Clarify the Provisional Claim Construction Order (Doc. No. 204) is **GRANTED**.

So ORDERED and SIGNED this 18th day of June, 2010.

JOHN D. LOVE
UNITED STATES MAGISTRATE JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

POZEN INC.	§	
	§	
Plaintiff,	§	
	§	
v.	§	**CIVIL ACTION No. 6:08cv437-LED-JDL**
	§	
PAR PHARMACEUTICAL, INC.,	§	**CONSOLIDATED with**
ALPHAPHARM PTY LTD,	§	**CIVIL ACTION No. 6:09cv003 and**
TEVA PHARMACEUTICALS	§	**CIVIL ACTION No. 6:09cv182**
USA INC.,	§	
DR. REDDY'S LABORATORIES, INC.	§	
	§	
Defendants.	§	

APPENDIX

U.S. PATENT Nos. 6,060,499, 6,586,458, and 7,332,183

Claim Language	Patent	Claims	Plaintiff's Proposed Construction	Defendants' Proposed Construction	Court's Construction
"by administering" "administered" "administering" "administering to said patient"	'499 patent '458 patent '183 patent	claims 1, 2, 3, 6, 7 and 9–27 claims 1, 2 ,5, and 6–24 claims 13–18 and 20	Ordinary and customary meaning. Alternatively, "to mete out."	Putting into a patient	Ordinary and customary meaning.
"concomitantly administering"	'499 patent	claims 1, 2, 3, 5–8, and 9–27	Simultaneous administration; or administration of a second drug for migraine relief while a first drug for migraine relief is present in a therapeutically effective amount; or administration of a 5-HT agonist and NSAID such that the effective plasma levels of the NSAID will be present in a subject from about one hour to about 12–24 hours after the onset of migraine or onset of precursor symptoms of a migraine.	Putting into a patient two (or more) compositions (i.e., drugs) such that: a) the drugs are put into a patient at the same time; or b) the second drug is put into a patient while the first drug is present in the patient in a therapeutically effective amount, or c) putting into a patient a 5-HT agonist and NSAID such that effective plasma levels of the NSAID will be present in a subject from about one hour to about 24 hours after the onset migraine or onset of precursor symptoms of a migraine.	Simultaneous administration; or administration of a second drug for migraine relief while a first drug for migraine relief is present in a therapeutically effective amount; or administration of a 5-HT agonist and NSAID such that the effective plasma levels of the NSAID will be present in a subject from about one hour to about 12–24 hours after the onset of migraine or onset of precursor symptoms of a migraine.

Claim Language	Patent	Claims	Plaintiff's Proposed Construction	Defendants' Proposed Construction	Court's Construction
"concomitantly administering"	'458 patent	claims 1, 2, 5, and 6–24	Given in close enough temporal proximity to allow their individual therapeutic effects to overlap.	Putting into a patient two (or more) compositions (i.e., drugs) such that they are "given in close enough temporal proximity to allow their individual therapeutic effects to overlap."	Given in close enough temporal proximity to allow their individual therapeutic effects to overlap.
"long-acting, non-steroidal, anti-inflammatory drug (LA-NSAID)"	'499 patent '458 patent	claims 1–8 claims 1, 3, 4, 5, 25, and 28	An NSAID with a pharmacokinetic half-life of at least about 4–6 hours and preferably about 8–14 hours and a duration of action equal to or exceeding about 6–8 hours.	A non-steroidal anti-inflammatory drug with a pharmacokinetic half-life of at least about 4–6 hours and a duration of action equal to or exceeding about 6–8 hours.	An NSAID with a pharmacokinetic half-life of at least about 4–6 hours and preferably about 8–14 hours and a duration of action equal to or exceeding about 6–8 hours.
"said LA-NSAID is naproxen"	'499 patent '458 patent	claims 13, 14, 15 and 26 claims 10, 11, 12, 23, 26, and 29	(S)-6-methoxy-α-methyl-2-naphthaleneacetic acid in any pharmaceutically acceptable form.	(S)-6-methoxy-α-methyl-2-naphthaleneacetic acid; does not mean (S)-6-methoxy-α-methyl-2-naphthaleneacetic acid, sodium salt.	(S)-6-methoxy-α-methyl-2-naphthaleneacetic acid or a pharmaceutically acceptable salt thereof.
"said LA-NSAID is naproxen or a pharmaceutically acceptable salt"	'458 patent	claim 11	(S)-6-methoxy-α-methyl-2-naphthaleneacetic acid in any pharmaceutically acceptable form or specifically in the form of a pharmaceutically acceptable salt.	(S)-6-methoxy-α-methyl-2-naphthaleneacetic acid or a pharmaceutically acceptable salt thereof.	(S)-6-methoxy-α-methyl-2-naphthaleneacetic acid or a pharmaceutically acceptable salt thereof.

Claim Language	Patent	Claims	Plaintiff's Proposed Construction	Defendants' Proposed Construction	Court's Construction
"said naproxen is in the form of a sodium salt"	'458 patent	claim 24	(S)-6-methoxy-α-methyl-2-naphthaleneacetic acid in any pharmaceutically acceptable form is specifically in the form of a sodium salt.	The chemical name for naproxen is (S)-6-methoxy-α-methyl-2-naphthaleneacetic acid sodium salt; does not mean (S)-6-methoxy-α-methyl-2-naphthaleneacetic acid.	(S)-6-methoxy-α-methyl-2-naphthaleneacetic acid or a pharmaceutically acceptable salt thereof.
"a multilayer pharmaceutical tablet"	'183 patent	claims 1–20	A pharmaceutical tablet with multiple distinct areas.	A pharmaceutical tablet with at least two separate, distinct layers; it does not include: tablets that are admixtures; any dosage forms other than tablets; tablets in which one drug is in a core and surrounded by a layer or coating containing the second drug; and tablets containing multiple drug release pellets or microparticles.	A pharmaceutical tablet with at least two separate, distinct layers.

Claim Language	Patent	Claims	Plaintiff's Proposed Construction	Defendants' Proposed Construction	Court's Construction
"substantially all of said triptan is in a first layer of said tablet and substantially all of said naproxen is in a second, separate layer"	'183 patent	claim 1	At least 90%, and preferably greater than 95%, of the total therapeutic agent present in the tablet is included within one distinct layer. "a first layer" means one or more distinct areas of triptan. "a second, separate layer" means one or more distinct areas of naproxen. The rest of the phrase is ordinary and customary meaning in light of the agreed construction for naproxen.	At least 90% of the total amount of triptan in the tablet is in a first distinct layer of the tablet and at least 90% of the total amount naproxen in the tablet is in a second distinct layer of the tablet.	At least 90%, and preferably greater than 95%, of the total triptan present in the tablet is included within one distinct layer and at least 90%, and preferably greater than 95%, of the naproxen present in the tablet is included within a second distinct layer.